FDA and the Reuse of Single Use Devices: Policy Moving Forward

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Objectives of Presentation

- Explain background of reuse issue
- Provide FDA's perspective on solutions
- Describe FDA's proposed change in regulatory strategy
- *Note that the issue of open but unused devices, a common practice in hospitals, has been taken "off the table": no longer part of FDA's reuse strategy*

FDA's Position Historically

- Reprocessing in Hospitals/Clinics (Compliance Policy Guide 300.500)
- Any Person Engaged in Single Use Device Reprocessing is a "Manufacturer"
- Premarket Submissions Have Not Been Requested

FDA's Position Historically
(continued)

- Requirements of 3rd Party Reprocessing Firms:
  - Device Registration and Listing, 21 CFR, Part 807
  - Good Manufacturing Practice (GMP) Inspection, 21 CFR, Part 820
  - Medical Device Reporting, 21 CFR, Part 803
  - General Labeling Requirements, 21 CFR, Part 801
- Reuse Policy Documents & Correspondence on FDA Web Page (www.fda.gov.reuse)

Simple Solutions?

- One voice in the debate suggests calling for identical regulatory controls for reprocessing as for OEMs - call for 510(k)s and PMAs
- An opposing voice suggests we leave General Controls in place as sufficient: Registration and Listing, GMP (Quality System Requirements), Labeling, and Medical Device Reporting
- Neither approach is satisfactory

Regulatory Strategy by Risk

Product Risk Category	Regulatory Requirements*^	Enforcement Date
"High-Risk" Products	**R & L; Premarket submissions w/in 6 months or Cease reprocessing**	**Enforcement action within 12 months**
"Moderate-Risk" Products	**R & L; Premarket submissions w/in 12 months**	**Enforcement action within 18 months**
"Low-Risk" Products	**R & L; Premarket submissions w/in 18 months**	**Within 2 years**

** Initially: third party reprocessors and hospitals*

^ Premarket submissions for non-exempt devices

Data Submissions

- Reprocessed SUDs should be labeled the same regardless of who does reprocessing
- FDA will examine the reuse of single use devices that creates a new single use device
- Procedures already exist for approving the change of a single use device to multiple use
- FDA still working on submission requirements
- FDA reconsidering “high risk” exempt products

Enforcement Approach

- Third party reprocessors will fall into usual approaches from FDA for manufacturers
- Hospitals may wish to continue to reprocess
  - For reuse of exempt products, hospitals will have to follow general controls (esp. GMP)
  - For non-exempt products, hospitals will have to submit premarket notification or approval
  - FDA partnering with JCAHO to monitor
- Other health care facilities will be considered

Vision for the Future

Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful; don't identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

- FDA approach will be risk and science based
- Premarket submissions will be required: projected date Jan 2001
- Horizontal and vertical standards could be useful
- Substantial outreach
- Leverage outside parties, e.g., JCAHO